



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 10/616,189 | 07/09/2003 | Milana M. Maletic | 21174 | 9676 |
| 7590 | 01/11/2006 | | EXAMINER | |
| Mollie M. Yang Merck & Co., Inc. Patent Dept., RY60-30 P. O. Box 2000 Rahway, NJ 07065-0907 | | | MCINTOSH III, TRAVISS C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1623 | |
| DATE MAILED: 01/11/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|---------------------------------------|--|
| Office Action Summary | Application No. 10/616,189 | Applicant(s) MALETIC ET AL. | |
| | Examiner Traviss C. McIntosh | Art Unit 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 9, drawn to compounds and compositions comprising the compound of formula Ia of claim 1, classified in class 514, subclass 23.
- II. Claim 10, drawn to a method of treating a bacterial infection by administering a compound of Group I to a patient, classified in class 514, subclass 23.
- III. Claims 2-4, drawn to methods of producing compounds of formula 7, classified in class 536, subclass 124.
- IV. Claims 5-6, drawn to methods of producing compounds of formula 4, classified in class 536, subclass 124.
- V. Claims 7 and 8, drawn to methods of preparing libraries of compounds of formula I and a library of compounds made by the methods of claim 7, classified in class 536, subclass 55.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

Art Unit: 1623

§ 806.05(h)). In the instant case the process for using the product can be practiced with another materially different product, such as by using erythromycin.

Inventions I and III are unrelated. In the instant case, Group I is drawn to specific compounds of formula Ia and Group III is drawn to methods of making compounds of formula 7, which are divergent in structure. It is noted that a reference anticipating or rendering obvious the compounds of group I would not necessarily anticipate or render obvious the methods of making the resin-bound compounds of group III, and as such, additional search and examination would be required.

Inventions I and IV are unrelated. In the instant case, Group I is drawn to specific compounds of formula Ia and Group IV is drawn to methods of making compounds of formula 4, which are divergent in structure. It is noted that a reference anticipating or rendering obvious the compounds of group I would not necessarily anticipate or render obvious the methods of making the resin-bound compounds of group IV, and as such, additional search and examination would be required.

Inventions I and V are unrelated. In the instant case, Group I is drawn to specific compounds of formula Ia and Group V is drawn to methods of making libraries of compounds of formula I, which are divergent in structure. It is noted that a reference anticipating or rendering obvious the compounds of group I would not necessarily anticipate or render obvious the methods of making the library of compounds of group V, and as such, additional search and examination would be required.

Invention II is unrelated to inventions III, IV, and V. Invention II is drawn to methods of treating bacterial infections using the compounds of formula Ia, and inventions III-V are drawn

Art Unit: 1623

to methods of producing divergent resin-compounds and libraries of compounds. It is noted that a reference anticipating or rendering obvious the methods of treatment of group II would not necessarily anticipate or render obvious the methods of making the divergent resin-bound compounds of groups III-IV or a library of compounds of group V, and as such, additional search and examination would be required.

Inventions III-V are unrelated. Inventions III-V are drawn to methods of making divergent compounds using divergent steps. It is noted that a reference anticipating or rendering obvious the methods of one group would not necessarily anticipate or render obvious the methods of making the divergent compounds of the other groups, or a library of compounds of group V, and as such, additional search and examination would be required.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper. It would indeed impose an undue burden upon the examiner in charge of this application if the instant restriction requirement is not set forth.

Claims 1-10 are generic to a plurality of disclosed patentably distinct species comprising a plethora of divergent compounds represented by the Markush groups of the various formulas. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. By a single species it is meant a single compound. The compound may be named in any of four ways: 1) according to IUPAC standard, 2) by a pictorial representation of the compound, 3) by setting forth the specific chemical group that each variable of the

Art Unit: 1623

Markush group represents, or 4) by naming a claim or an example which itself sets forth a single compound.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §

Art Unit: 1623

821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Art Unit: 1623

Due to the complexity of the instant restriction requirement, no telephone call was made to request an oral election to the above restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

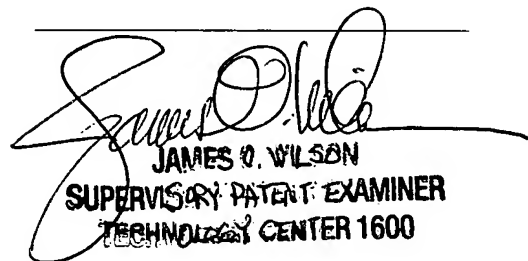
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
January 6, 2006

Shaojia A. Jiang
Supervisory Patent Examiner
Art Unit 1623



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600